

AMENDED IN ASSEMBLY JULY 11, 2002

AMENDED IN ASSEMBLY JULY 1, 2002

AMENDED IN SENATE APRIL 15, 2002

AMENDED IN SENATE APRIL 4, 2002

**SENATE BILL**

**No. 1809**

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**Introduced by Senator Machado**  
(Coauthor: Assembly Member Salinas)

February 22, 2002

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An act to amend Section 1300 of, and to add Section 1260.3 to, the Business and Professions Code, relating to healing arts, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 1809, as amended, Machado. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory health care personnel by the State Department of Health Services.

This bill would create a new license category for a medical laboratory technician who would be authorized to perform waived and moderate complexity tests or examinations while working under the supervision of a physician and surgeon or certain other licensed persons, and to report the test results. The bill would require the department to issue a medical laboratory technician license to each person who pays the license fee and meets specified licensure requirements. The bill would also require the department to adopt emergency regulations to implement licensure of medical laboratory technicians as soon as possible, and would authorize the department to establish licensing and

renewal fees that do not exceed the costs of the department for the program.

The bill would declare that it is to take effect immediately as an urgency statute.

Vote: <sup>2</sup>/<sub>3</sub>. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. It is the intent of the Legislature, in enacting this  
2 act, to begin to address the critical laboratory personnel shortage  
3 in California. The Legislature further finds and declares the  
4 following:

5 (a) Between 70 percent and 85 percent of all physician  
6 diagnosis and treatment decisions are based upon clinical  
7 laboratory test results.

8 (b) California faces a shortage of over 7,000 laboratory  
9 personnel over the next 10 years.

10 (c) Current California training programs supply fewer than 100  
11 new laboratory staff persons per year.

12 (d) There is a lack of public understanding of clinical  
13 laboratory science and a need for better educational counseling of  
14 potential laboratory personnel.

15 (e) The absence of qualified persons conducting clinical  
16 laboratory tests would have life or death consequences for the  
17 public.

18 (f) The demand for clinical laboratory services is real and  
19 growing with the aging of our population. At the same time, a  
20 majority of the qualified clinical laboratory personnel in the state  
21 are reaching retirement age.

22 (g) The shortage of personnel in the clinical laboratory  
23 profession necessitates the development of a career ladder to  
24 develop a supply of personnel to the clinical laboratory field.

25 In light of the above findings, the Legislature recognizes that  
26 creation of the medical laboratory technician category is a small  
27 but necessary step to address the severe clinical laboratory  
28 personnel shortages in California.

29 SEC. 2. Section 1260.3 is added to the Business and  
30 Professions Code, to read:



1 1260.3. (a) The department shall issue a medical laboratory  
2 technician license to each person who meets the following  
3 requirements:

4 (1) Has met the requirements of this chapter and any reasonable  
5 qualifications established by regulations of the department,  
6 including, but not limited to, any of the following:

7 (A) Lawfully holds an associate degree or an equivalent or  
8 higher degree in chemical, physical, biological, or ~~chemical~~  
9 *clinical* laboratory science, which includes a minimum of 36  
10 semester units of physical or biological sciences.

11 (B) The completion of 60 semester (90 quarter) units from an  
12 accredited college or university, with 36 semester units in physical  
13 or biological sciences.

14 (C) Graduation from a medical laboratory technician training  
15 program accredited by the National Accrediting Agency for  
16 Clinical Laboratory Sciences or other recognized accrediting  
17 program approved by the department.

18 (D) Graduation from an advanced military medical laboratory  
19 specialist program approved by the department.

20 (2) Has applied for the license on forms provided by the  
21 department.

22 (3) Has paid a license fee established in regulations of the  
23 department in accordance with subdivision (v) of Section 1300.

24 (b) A licensed medical laboratory technician may perform  
25 clinical laboratory tests or examinations classified as waived or of  
26 moderate complexity under CLIA, and may report the test results.  
27 However, a licensed medical laboratory technician shall not  
28 perform microscopic analysis or immunohematology procedures.  
29 The medical laboratory technician shall work under the  
30 supervision of a licensed physician and surgeon or a baccalaureate,  
31 masters, or doctoral level person licensed pursuant to this chapter.  
32 The supervision shall be required during the entire time a medical  
33 laboratory technician performs clinical laboratory tests or  
34 examinations.

35 (c) The department shall adopt emergency regulations to  
36 implement this section as soon as possible.

37 SEC. 3. Section 1300 of the Business and Professions Code  
38 is amended to read:

39 1300. The amount of application, registration, and license  
40 fees under this chapter shall be as follows:

1 (a) The application fee for a histocompatibility laboratory  
2 director's, clinical laboratory bioanalyst's, clinical chemist's,  
3 clinical microbiologist's, clinical laboratory toxicologist's,  
4 clinical cytogeneticist's, or clinical molecular biologist's license  
5 is thirty-eight dollars (\$38). This fee shall be sixty-three dollars  
6 (\$63) commencing on July 1, 1983.

7 (b) The annual renewal fee for a histocompatibility laboratory  
8 director's, clinical laboratory bioanalyst's, clinical chemist's,  
9 clinical microbiologist's, or clinical laboratory toxicologist's  
10 license is thirty-eight dollars (\$38). This fee shall be sixty-three  
11 dollars (\$63) commencing on July 1, 1983.

12 (c) The application fee for a clinical laboratory scientist's or  
13 limited clinical laboratory scientist's license is twenty-three  
14 dollars (\$23). This fee shall be thirty-eight dollars (\$38)  
15 commencing on July 1, 1983.

16 (d) The application and annual renewal fee for a  
17 cytotechnologist's license shall be fifty dollars (\$50) commencing  
18 on January 1, 1991.

19 (e) The annual renewal fee for a clinical laboratory scientist's  
20 or limited clinical laboratory scientist's license is fifteen dollars  
21 (\$15). This fee shall be twenty-five dollars (\$25) commencing on  
22 July 1, 1983.

23 (f) The application fee for a clinical laboratory license is six  
24 hundred dollars (\$600).

25 (g) The annual renewal fee for a clinical laboratory license is  
26 five hundred fifty-seven dollars (\$557).

27 (h) The application fee for a certificate of accreditation issued  
28 pursuant to Section 1223 is one hundred fifty dollars (\$150).

29 (i) The annual renewal fee for a certificate of accreditation  
30 issued pursuant to Section 1223 is one hundred dollars (\$100).

31 (j) In addition, clinical laboratories providing cytology  
32 services shall pay an annual fee that shall be set by the department  
33 in an amount needed to meet but not exceed the department's costs  
34 of proficiency testing and special site surveys for these  
35 laboratories, and that shall be based upon the volume of cytologic  
36 slides examined by a laboratory. If the amount collected is less than  
37 or exceeds the amount needed for these purposes, the amount of  
38 fees collected from those laboratories in the following year shall  
39 be adjusted accordingly.

1 (k) The application fee for a trainee's license is eight dollars  
2 (\$8). This fee shall be thirteen dollars (\$13) commencing on July  
3 1, 1983.

4 (l) The annual renewal fee for a trainee's license is five dollars  
5 (\$5). This fee shall be eight dollars (\$8) commencing on July 1,  
6 1983.

7 (m) The application fee for a duplicate license is three dollars  
8 (\$3). This fee shall be five dollars (\$5) commencing on July 1,  
9 1983.

10 (n) The delinquency fee is equal to the annual renewal fee.

11 (o) The director may establish a fee for examinations required  
12 under this chapter. The fee shall not exceed the total cost to the  
13 department in conducting the examination.

14 (p) The certification and renewal fees for hemodialysis  
15 technicians certified under subdivision (a) of Section 1247.6 shall  
16 be fifty dollars (\$50).

17 (q) The annual fee for a clinical laboratory subject to  
18 registration under paragraph (2) of subdivision (a) of Section 1265  
19 and performing only those clinical laboratory tests or  
20 examinations considered waived under CLIA is fifty dollars (\$50).  
21 The annual fee for a clinical laboratory subject to registration  
22 under paragraph (2) of subdivision (a) of Section 1265 and  
23 performing only provider-performed microscopy, as defined  
24 under CLIA is seventy-five dollars (\$75). A clinical laboratory  
25 performing both waived and provider-performed microscopy  
26 shall pay an annual registration fee of seventy-five dollars (\$75).

27 (r) The costs of the department in conducting a complaint  
28 investigation, imposing sanctions, or conducting a hearing under  
29 this chapter shall be paid by the clinical laboratory. The fee shall  
30 be no greater than the fee the laboratory would pay under CLIA for  
31 the same type of activities and shall not be payable if the clinical  
32 laboratory would not be required to pay those fees under CLIA.

33 (s) The state, a district, city, county, city and county, or other  
34 political subdivision, or any public officer or body shall be subject  
35 to the payment of fees established pursuant to this chapter or  
36 regulations adopted thereunder.

37 (t) In addition to the payment of registration or licensure fees,  
38 a clinical laboratory located outside the State of California shall  
39 reimburse the department for travel and per diem to perform any

1 necessary onsite inspections at the clinical laboratory in order to  
2 ensure compliance with this chapter.

3 (u) Whenever a clinical laboratory has paid registration or  
4 compliance fees, or both, to HCFA under CLIA for the same  
5 period of time for which a license is issued under Section 1265, the  
6 fee required for the clinical laboratory license under subdivision  
7 (f) or (g), and as adjusted pursuant to Section 100450 of the Health  
8 and Safety Code, shall be reduced by the percentage of the total of  
9 all CLIA registration and compliance fees paid to HCFA by all  
10 California laboratories that are made available to the department  
11 to carry out its functions as a CLIA agent in the federal fiscal year  
12 immediately prior to when the license fee is due.

13 (v) The department shall establish an application fee and a  
14 renewal fee for a medical laboratory technician license, the total  
15 fees collected not to exceed the costs of the department for the  
16 implementation and operation of the program licensing and  
17 regulating medical laboratory technicians pursuant to Section  
18 1260.3.

19 SEC. 4. This act is an urgency statute necessary for the  
20 immediate preservation of the public peace, health, or safety  
21 within the meaning of Article IV of the Constitution and shall go  
22 into immediate effect. The facts constituting the necessity are:

23 The severe shortage of clinical laboratory personnel, especially  
24 personnel licensed as clinical laboratory scientists or limited  
25 clinical laboratory scientists, is creating the potential for a crisis in  
26 clinical laboratory testing capacity. A new licensure category for  
27 laboratory personnel qualified to perform waived and moderately  
28 complex testing in a clinical laboratory, the medical laboratory  
29 technician, is necessary to provide sufficient personnel capacity to  
30 deal with the current testing needs of the public. In addition, any  
31 catastrophic biological event, event of bioterrorism, or public  
32 health epidemic could not be optimally handled given the current  
33 shortage of clinical laboratory testing capacity.

34 In order for the residents of the state to benefit from additional  
35 qualified personnel to perform appropriate testing activities in  
36 clinical laboratories as soon as possible, and in order to provide  
37 sufficient personnel to deal with these events, it is necessary that  
38 this act take effect immediately.

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